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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,341	TANAKA ET AL.	
	Examiner	Art Unit	
	Allison M Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a cell culture/transfection device, classified in class 435, subclass 305.2.

II. Claims 14-26, drawn to a kit comprising a cell transfection device, eukaryotic cells and at least one nucleic acid, classified in class 424, subclass 93.1.

III. Claims 27-50, drawn to a method for transfecting eukaryotic cells, classified in class 435, subclass 402.

IV. Claims 51-64, drawn to a method for determining whether a biomolecule can enter a cell, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the kit of Group II (the "combination") as claimed does not require the particulars of the cell culture/transfection device of Group I (the "subcombination") as claimed because any suitable culture device can be used as the container-component of the kit. For example, any suitable cell culture grade plasticware vessel can be used to transfect cells, transfection does not require the specific cell transfection device of Group I that comprises a solid surface coated with calcium chloride in a gel matrix. Therefore the kit (the "combination") can comprise any suitable cell culture vessel; it does not require the particular cell transfection device of claim 10. Additionally, the cell culture/transfection device of group I (the "subcombination") has separate utility such as regular cell culture for the purpose of cell line maintenance and expansion; the elements

included in the cell culture/transfection device are common elements used cell culture, including trace amounts of metal salts, matrix complexes, and proteins. Finally, the device of Group I in its simplest form is only a vessel; it could alternatively be used to store inert objects, such as loose change.

Inventions III and IV are distinct inventions and thus are subject to restriction. The inventions are distinct processes in that the methods are not dependent on each other, not to be used together and have different functions, modes of operation, and effects. In the instant case the methods have different requirements within their steps, sufficient to differentiate the methodologies. The method of Group III requires the solid surface for transfection of the eukaryotic cells to be at least partially coated with a composition comprising a metal salt, which is distinct from the coating of the solid substrate used in the method of Group IV. The method of Group IV requires the solid surface to be coated with a polymer or lipid, which is distinct from the coating of the solid substrate used in the method of Group III. Additionally, the methods have different effects, the method of Group III is intended to transfect cells; the method of Group IV is not intended to transfect cells, but rather to determine if certain biomolecules can enter a cell; therefore the method of Group IV does not require the end product to be a transfected cell.

Invention I is related to Inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cell culture/transfection device of Group I can be used in either method III or IV, which methods have been previously shown to be distinct. Therefore the cell culture/transfection device of Group I can be used in materially different processes and is not specific for either process.

Inventions II is related to Inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Groups III and IV can be practiced without the kit of Group II. Though the kit of Group II neatly packages three of the essential elements required in the methods of Groups III and IV, it is not required that the cell transfection device, the eukaryotic cells and the at least one nucleic acid come from a pre-packaged kit; rather one could obtain each of the needed components separately and still perform the methods of Groups III and IV.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

Additionally, the following election of species need to be made upon the election of the respective Group:

Upon election of Group I:

1. Claim 7 is generic to a plurality of disclosed patentably distinct species of matrix consisting of proteins, glycoproteins, peptides, polysaccharides, and polymers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. Upon the election of "proteins" as the species of matrix from claim 7, a further election of species is required from claim 8, which is generic to a plurality of disclosed patentably distinct species of proteins, consisting of: gelatin, collagen, laminin, fibronectin, and bovine serum albumin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

3. Upon the election of "polymers" as the species of matrix from claim 7, a further election of species is required from claim 9, which is generic to a plurality of disclosed patentably distinct species of polymers, consisting of: hydrogels, biodegradable polymers, and biocompatible materials. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon election of Group II:

1. Claim 14 is generic to a plurality of disclosed patentably distinct species of eukaryotic cells consisting of: mammalian cells (claim 15), dividing cells (claim 16), non-dividing cells (claim 16), transformed cells (claim 17), primary cells (claim 17), somatic cells (claim 18), stem cells (claim 18), plant cells (claim 19), and insect cells (claim 20). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. Claim 21 is generic to a plurality of disclosed patentably distinct species of nucleic acid consisting of: DNA, RNA, DNA/RNA hybrid and chemically modified nucleic acids. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon election of Group III:

1. Claim 35 is generic to a plurality of disclosed patentably distinct species of matrix consisting of proteins, glycoproteins, peptides, polysaccharides, and polymers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. Upon the election of "proteins" as the species of matrix from claim 35, a further election of species is required from claim 36, which is generic to a plurality of disclosed patentably distinct species of proteins, consisting of: gelatin, collagen, laminin, fibronectin, and

bovine serum albumin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

3. Upon the election of "polymers" as the species of matrix from claim 35, a further election of species is required from claim 37, which is generic to a plurality of disclosed patentably distinct species of polymers, consisting of: hydrogels, biodegradable polymers, and biocompatible materials. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

4. Claim 27 is generic to a plurality of disclosed patentably distinct species of eukaryotic cells consisting of: mammalian cells (claim 39), dividing cells (claim 40), non-dividing cells (claim 40), transformed cells (claim 41), primary cells (claim 41), somatic cells (claim 42), stem cells (claim 42), plant cells (claim 43), and insect cells (claim 44). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

5. Claim 45 is generic to a plurality of disclosed patentably distinct species of nucleic acid consisting of: DNA, RNA, DNA/RNA hybrid and chemically modified nucleic acids. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Upon the election of Group IV:

1. Claim 51 is generic to a plurality of disclosed patentably distinct species of biomolecules consisting of: nucleic acids, proteins, peptides, sugars, polysaccharides, and organic compounds. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

2. Upon the election of "nucleic acids" as the species of biomolecule from claim 52, a further election of species is required from claim 53, which is generic to a plurality of disclosed patentably distinct species of nucleic acids, consisting of: DNA, RNA, DNA/RNA hybrids and chemically modified nucleic acids. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

3. Claim 51 is generic to a plurality of disclosed patentably distinct species of eukaryotic cells consisting of: mammalian cells (claim 59), dividing cells (claim 60), non-dividing cells (claim 60), transformed cells (claim 61), primary cells (claim 61), somatic cells (claim 62), stem cells (claim 62), plant cells (claim 63), and insect cells (claim 64). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse any of the elections on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

An election must be made in response to this office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651